

REMARKS

Applicants have cancelled claims 1, 2, 4-10 and 21 (claims 1-21 are now cancelled). Newly submitted claims 22-30 are pending. In view of these amendments and the remarks that follow, reconsideration and withdrawal of the Examiner's rejections is respectfully requested.

The newly added claims are directed to a method for diagnosing pathological conditions in a human patient using ion mobility spectrometry to determine the amounts of biogenic amines contained in a biological sample obtained from the patient. Such an analysis can be used to diagnose, for example, certain vaginal disorders such as bacterial vaginosis. The specification discloses the use of IMS for the diagnosis of various diseases or pathological conditions (U.S. Published Appln. No. 2002/0102627 at ¶¶ 53-64), specifically vaginal disorders (*Id.* at ¶¶ 9, 20 and 65), and particularly bacterial vaginosis (*Id.* at original claim 5 and ¶ 20). Biogenic amines useful in diagnosis include trimethylamine (*Id.* at original claim 5), putrescine and cadaverine (*Id.* at ¶ 65 and original claim 7). Paragraphs 20-21 of the present application discuss calculating the "equivalent ratio" of the number of ions of a given amine as compared to the total number of amine ions, if the number of TMA ions is 40% or more of the total amine ions, the presence of bacterial vaginosis is recognized, while 20% or less and the absence is recognized. Accordingly, the newly added claims are fully supported by the originally filed application and do not contain new matter.

Claims 1 and 2 have been rejected under 35 U.S.C. § 102(b) as anticipated by *Baumbach et al.*, "Ion Mobility Spectrometry: Arriving on Site and Moving Beyond a Low Profile." The Examiner has determined that *Baumbach* "teaches the use of ion mobility spectrometry to test for amines in biological samples." Applicants respectfully disagree.

First, this rejection is moot with respect to claims 1 and 2, which have been cancelled. However, *Baumbach* provides an overview of the state of the art of ion mobility spectrometry (IMS) and a general discussion of applications for this technique. See *Baumbach* at page 344A, column 3 to page 345, column 2. The primary uses described are for the detection of chemical warfare agents and explosives. In Table I at page 374A, *Baumbach* discloses a number of additional applications "which have been developed and categorized under laboratory or controlled environments but which have not been extensively employed in any industrial or environmental venues." There is no disclosure, however, of the detection of ions formed by biogenic amines by IMS for diagnostic purposes, let alone for the diagnosis of vaginal disorders such as bacterial vaginosis. Accordingly, the *Baumbach* reference does not anticipate the pending claims.

Moreover, the inclusion of "amines" in table I of *Baumbach* is supported by the following two references: *Karpas*, "Ion Mobility Spectrometry of Aliphatic and Aromatic Amines," *Anal. Chem.* 61, 684 (1989) ("*Karpas I*"); and *Karpas et al.*, "The Structure of Protonated Diamines and Polyamines," *Struct. Chem.*, Vol. 5, No. 2, 135 (1994) ("*Karpas II*"), copies of which have been submitted in connection with the accompanying Information Disclosure Statement. *Karpas I* generally discloses the use of IMS to compare the mobility spectra for a wide range of aliphatic and aromatic amines. *Karpas II* discloses the use of IMS to investigate the structure of certain diamines and polyamines. Neither of these references relied upon by *Baumbach* even mentions the detection of ions formed by biogenic amines by IMS for diagnostic purposes.

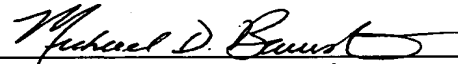
As it is believed that all of the rejections set forth in the Official Action have been fully met, favorable reconsideration and allowance are earnestly solicited.

If, however, for any reason the Examiner does not believe that such action can be taken at this time, it is respectfully requested that he/she telephone Applicants' attorney at (908) 654-5000 in order to overcome any additional objections which he might have.

If there are any additional charges in connection with this requested amendment, the Examiner is authorized to charge Deposit Account No. 12-1095 therefor.

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Respectfully submitted,

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